DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Tornier
Mr. Damien Guillaud
Regulatory Affairs Specialist
161, rue Lavoisier – Montbonnot
38334 Saint Ismier Cedex
FRANCE

Re: K081059
Trade/Device Name: Aequalis Reversed Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: June 16, 2008
Received: June 20, 2008

Dear Mr. Guillaud:

This letter corrects our substantially equivalent letter of July 17, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *Aequalis Reversed Shoulder Prosthesis*

Indications For Use:

The Aequalis Reversed Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable ~~rotator cuff-tear. Only the humeral~~ components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.

When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of Aequalis Reversed range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081059/S1

K081059

JUL 17 2008

TORNIER

Implants Chirurgicaux

Summary of Safety and Effectiveness information
Special 510(k) Premarket Notification – Aequalis Reversed Shoulder Prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***AEQUALIS Reversed Shoulder Prosthesis***
Common name:	Total-Shoulder System and Hemi-Shoulder System
Classification name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mr Damien Guillaud
Regulatory affairs Specialist
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4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS

5) Equivalent / Predicate device

Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941, K041873, K050316, K061439
Aequalis Shoulder System, TORNIER SA, K952928, K012212, K041339, K060209

6) Device description

The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.
Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these

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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.
The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

The present device modification submission consists in :
- addition of glenoid baseplates and glenoid spheres,
- addition of polyethylene inserts.

7) Materials
The base of the glenoid implant is manufactured from Titanium alloy. The sphere is manufactured from Cobalt-Chromium alloy and the screw is manufactured from Titanium alloy.
The hydroxylapatite coating conforms to the ASTM standard F 1185. The coating is performed by BioCoat, Inc. according to their Master File MAF-339.
Metaphyseal inserts are made of ultra-high molecular weight polyethylene (UHMWPE).

8) Indications
The Aequalis Reversed Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.
When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.
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